Current Agreements

Dealdoc

Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

Adolor
GSK

Sep 16 2009

Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

Companies:	Adolor GSK
Announcement date:	Sep 16 2009
Related contracts:	Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Termination of licensing, co-development and marketing agreement for Entereg (alvimopan) Third amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Second amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan) Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated) Distribution agreement for Entereg (alvimopan) First amendment to distribution agreement for Entereg (alvimopan)

Details

Announcement date:	Sep 16 2009
Start date:	Sep 16 2009
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	Gastrointestinal » Symptoms » Bowel movement
Technology types:	Drug delivery Small molecules
Deal components:	Co-development Co-market Co-promotion Licensing Marketing Promotion
Stages of development:	Phase III
Geographic focus:	Worldwide

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NO. 5 TO

COLLABORATION AGREEMENT

THIS AMENDMENT NO. 5 TO COLLABORATION AGREEMENT (this “Amendment No. 5”), effective as of December 16, 2009 (the “Effective Date”), is made by and between ADOLOR CORPORATION, a Delaware corporation and having its principal office at 700 Pennsylvania Drive, Exton, Pennsylvania 19341 (“Adolor”), and GLAXO GROUP LIMITED, a United Kingdom corporation and having its principal office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom (“GSK”). Adolor and GSK are each sometimes referred to individually as a “Party” and together as the “Parties.”

WHEREAS, Adolor and GSK entered into that certain Collaboration Agreement dated April 14, 2002 (the “Collaboration Agreement”), as amended by Amendment No. 1 to the Collaboration Agreement effective on June 24, 2003 (“Amendment No. 1”), Amendment No. 2 to the Collaboration Agreement effective on December 22, 2004 (“Amendment No. 2”), Amendment No. 3 to the Collaboration Agreement effective on June 9, 2008 (“Amendment No. 3”), Amendment No. 4 to the Collaboration Agreement dated January 30, 2009 and effective as of January 1, 2009 (“Amendment No. 4”) and a Notice of Termination for GI Products dated August 29, 2008 (the “Notice”) (the Collaboration Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3, Amendment No. 4 and the Notice are collectively referred to herein as, the “Agreement”).

WHEREAS, GSK desires to terminate the Agreement with respect to the POI Product in all territories other than the United States, Puerto Rico, Guam and the U.S. Virgin Islands; and

WHEREAS, Adolor and GSK desire to amend the Agreement to reflect that the ROW means Puerto Rico, Guam and the U.S. Virgin Islands.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, Adolor and GSK, intending to be legally bound, hereby agree as follows:

1. Interpretation. Capitalized terms used herein and not otherwise defined shall have the meanings given to them in the Agreement.

2. ROW Defined. Subject to Section 15 of this Amendment No. 5, the definition of “ROW” in Section 1.122 of the Agreement is hereby deleted in its entirety and replaced with the following:

‘“ROW” means Puerto Rico, Guam and the U.S. Virgin Islands; for clarity, Countries other than the United States, Puerto Rico, Guam and the U.S. Virgin Islands are deemed to be outside of the ROW, and thus are not covered by the Agreement or this Amendment No. 5.’

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3. United States Defined. Subject to Section 15 of this Amendment No. 5, the definition of “United States” in Section 1.145 of the Agreement is hereby deleted in its entirety and replaced with the following:

‘“United States” means the fifty (50) states of the United States of America and the District of Columbia; for clarity, the United States does not include Puerto Rico, Guam and the U.S. Virgin Islands, which are included in the ROW.’

4. Termination of the POI Product in Countries other than ROW and United States. The Agreement by and between the Parties is hereby terminated with respect to the POI Product in Countries other than ROW and United States and GSK acknowledges and agrees that it has no rights to the POI Product in Countries other than the United States and ROW.

5. Availability of U.S. Sales Training For ROW. The following sentence shall be added at the end of Section 5.10.1:

“For the avoidance of doubt, GSK shall have the right to have its Sales Representatives and other sales and marketing personnel, in each case who are located in the ROW, participate in the training programs of Adolor in the United States for the purpose of ensuring overall consistency in the training programs for Collaboration Products.”

6. Availability of U.S. Sales Training Materials For ROW. Section 5.10.2 of the Agreement shall be deleted in its entirety and replaced with the following:

“Assistance. During the United States Term and during the ROW Term with respect to the ROW, each Party shall make available to the other Party for use in connection with Co-Promoting the Collaboration Products in the ROW, to the extent reasonable, assistance and services relating to such Co-Promotion, including, but not limited to, providing the other Party, free of charge and in a timely manner, with a master copy of such training materials relating to Collaboration Products as such Party has used and/or intends to use in connection with the training of its Sales

Representatives, including but not limited to learning units and any other printed, audio and video training materials. To the extent the other Party wishes to use such training materials in the training of its own Sales Representatives, it will be responsible for reproducing such training materials."

7. ROW Royalties For Adolor Products. The first sentence of Section 6.4.1 of the Agreement shall be deleted in its entirety and replaced with the following:

"Within thirty (30) days after the end of each Calendar Quarter, GSK shall pay Adolor royalty payments based on Net Sales of Adolor Products in such Calendar Quarter in the ROW during the ROW Term equal to the ROW Adolor Product Royalty set forth on Schedule 1 to Amendment No. 5, for Adolor Products; provided, however, that the royalty to be paid by GSK to Adolor on Net Sales of the POI Product in the ROW during the ROW Term shall be equal to the ROW POI Product Royalty set forth on Schedule 1 to Amendment No. 5."

8. Supply of Adolor Products. Section 10.8.1 shall be amended and updated to insert "and ROW" after any reference to the term "United States" contained in Section 10.8.1.

9. Supply of Collaboration Products for the ROW. Section 10.8.3 of the Agreement shall be deleted in its entirety.

10. Product Suppliers. The last sentence of Section 10.10 of the Agreement shall be deleted in its entirety.

11. Indemnification by GSK. Subsection (d) contained in Section 14.1 shall be deleted in its entirety and replaced with the following:

"(d) the manner in which GSK sells the Collaboration Product in the ROW"

12. Product Liability Claims in the United States. Section 14.5.1 shall be amended and updated to insert "and ROW" after any reference to the term "United States" contained in Section 10.8.1 (other than when used to reference the defined term "United States Term"). Additionally, the last sentence of Section 14.5.1 shall be deleted in its entirety and replaced with the following:

"Notwithstanding the foregoing, and except with respect to Collaboration Product sold by Adolor to GSK for sales in the ROW, Adolor shall not be responsible for any Losses arising out of or resulting from Product Liability Claims in relation to Collaboration Product for which it does not receive a percentage of the Adolor Product Marketing Contribution or a percentage of the GI Product Marketing Contribution unless such Loss is related to a Claim under Section 14.2(a) or 14.2(b)."

13. E.A.S.E.™ Program. For the purposes of this Amendment No. 5, the "E.A.S.E.™ Program" means the then-current ENTEREG Access Support and Education (E.A.S.E.™) Program implemented by the Parties as part of the Risk Evaluation and Mitigation Strategy approved by the FDA for the POI Product.

(a) Hospital Registrations. GSK shall, in accordance with the requirements of the E.A.S.E.™ Program, introduce, educate and cause all parties that seek to order the POI Product in the ROW to first apply for registration in the E.A.S.E.™ Program. Adolor shall, at no additional cost to GSK, maintain and manage the E.A.S.E.™ Program including the determination of whether a party's application for registration in the E.A.S.E. ™ Program will be accepted (a "Registered Entity"), to ensure that registration of hospitals in the ROW occurs in a manner substantially similar to that in the United States. In a manner and frequency that is mutually agreeable, Adolor shall provide to GSK a listing of all Registered Entities in the ROW. Further, Adolor hereby grants to GSK the right to use and distribute the E.A.S.E.™ Program educational materials to introduce, educate and register into the E.A.S.E.™ Program all eligible hospitals located in the ROW.

(b) Registered Hospital Verification. Prior to shipping the POI Product in the ROW, GSK shall ensure that the recipient of the POI Product is a Registered Entity. GSK shall not ship the POI Product to any party other than a Registered Entity.

(c) Further Assurances. Each Party shall cooperate reasonably with the other Party in implementing and maintaining the E.A.S.E.™ Program in the ROW, including, without limitation, promptly: (i) identifying, notifying Adolor of, and investigating instances of non-compliance with the E.A.S.E.™ Program, (ii) collecting, processing, and reporting to the other Party data necessary for the administration of the E.A.S.E.™ Program, (iii) updating the E.A.S.E.™ Program and its associated materials in the ROW, and (iv) implementing such other measures are as reasonable or appropriate under the circumstances.

14. Sales Representative FTE Requirements. For the avoidance of doubt, GSK's deployment of its personnel in the ROW shall have no effect on the calculation of its Sales Representative FTE Requirements for the POI Product in the United States under the Agreement.

15. Articles 7, 8 and 9. Solely for the purposes of Article 7, entitled, "Promotional Materials and Samples", Article 8, entitled "Information Concerning The Collaboration Products", and Article 9, entitled, "Regulatory Matters", Puerto Rico, Guam, and the U.S. Virgin Islands shall be considered to be a part of the United States, and not a part of the ROW.

16. Miscellaneous. This Amendment No. 5 shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of Delaware notwithstanding the provisions governing conflict of laws under such Delaware law to the contrary. This Amendment

No. 5 may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document. This Amendment No. 5 may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures. The Parties acknowledge and agree that the Agreement, as amended, shall supplement the terms and conditions of the Supply Agreement between Adolor and GSK, dated of even date herewith, (including, without limitation, with respect to the supply of POI Product in the ROW, information required to be shared by the Parties, and indemnification by the Parties). Except as set forth in this Amendment No. 5, the Agreement shall remain in full force and effect, except that each reference to the “Agreement” or words of like import in the Agreement will mean and be a reference to the Agreement as amended by this Amendment No. 5.

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amendment No. 5 to Collaboration Agreement as of the Effective Date.

GLAXO GROUP LIMITED

By:

/s/ Paul Williamson

Name: Paul Williamson

Title: For and on behalf of Edinburgh Pharmaceutical Industries Limited Corporate Director

ADOLOR CORPORATION

By:

/s/ Stephen W. Webster

Name: Stephen W. Webster

Title: Senior Vice President and Chief Financial Officer